

# ACEPROMAZINE MALEATE- acepromazine maleate tablet Covetrus North America

## Acepromazine Maleate Tablets

For use in dogs only.

### Caution:

Federal law restricts this drug to use by or on the order of a licensed veterinarian.

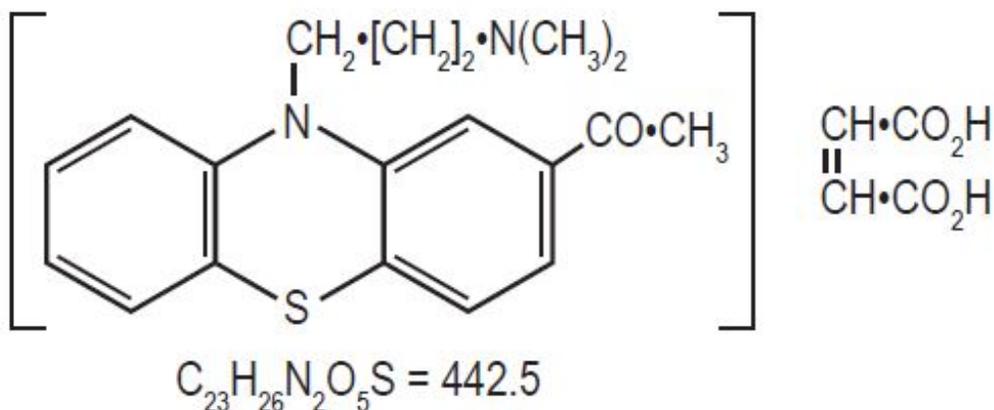
### Description:

Acepromazine maleate, a potent neuroleptic agent with a low order of toxicity, is of particular value in the tranquilization of dogs. Its rapid action and lack of hypnotic effect are added advantages.

### Chemistry:

2-acetyl-10-(3-dimethylaminopropyl) phenothiazine hydrogen maleate.

Acepromazine Maleate



### Mode of Action:

Acepromazine maleate has a depressant effect on the central nervous system and therefore causes sedation, muscular relaxation and a reduction in spontaneous activity. It acts rapidly, exerting a prompt and pronounced calming effect. It is an effective preanesthetic agent and lowers the dosage requirement of general anesthetics.

### Indications:

As an aid in tranquilization and as a preanesthetic agent in dogs.

Acepromazine Maleate Tablets can be used as an aid in controlling intractable animals during examination, treatment, grooming, x-ray and minor surgical procedures.

### **Dosage and Administration:**

Dogs: 0.25-1.0 mg/lb of body weight. Dosage may be repeated as required.

### **Animal Safety:**

Acute and chronic toxicity studies have shown a very low order of toxicity for acepromazine maleate.

A safety study using elevated dosages of acepromazine maleate demonstrated no adverse reactions even when administered at three times the upper limit of the recommended daily dosage (3.0 mg/lb body weight). The clinical observation for this high dosage was mild depression which disappeared in most dogs 24 hours after termination of dosing.

The only occurrence of adverse reaction during numerous clinical trials was a very mild respiratory distress (reverse sneeze) which was transient in nature and had no effect on the desired action of the drug.

### **Contraindications:**

Phenothiazines may potentiate the toxicity of organophosphates. Therefore, do not use acepromazine maleate to control tremors associated with organic phosphate poisoning.

Do not use in conjunction with organophosphorus vermifuges or ectoparasiticides, including flea collars.

Do not use with procaine hydrochloride.

### **Warning:**

Do not use in animals intended for human consumption.

Keep Acepromazine Maleate Tablets in a secure location out of reach of dogs, cats, and other animals to prevent accidental ingestion or overdose.

### **Precautions:**

Tranquilizers are potent central nervous system depressants, and they can cause marked sedation with suppression of the sympathetic nervous system. Tranquilizers can produce prolonged depression or motor restlessness when given in excessive amounts or when given to sensitive animals.

Tranquilizers are additive in action to the actions of other depressants and will potentiate general anesthesia. Tranquilizers should be administered in smaller doses and with greater care during general anesthesia and also to animals exhibiting symptoms of stress, debilitation, cardiac disease, sympathetic blockade, hypovolemia or shock. Acepromazine, like other phenothiazine derivatives, is detoxified in the liver; therefore, it

should be used with caution on animals with a previous history of liver dysfunction or leukopenia.

Epinephrine is contraindicated for treatment of acute hypotension produced by phenothiazine-derivative tranquilizers since further depression of blood pressure can occur.

Phenothiazines should be used with caution when followed by epidural anesthetic procedures because they may potentiate the arterial hypotensive effects of local anesthetics.

### **Adverse Reactions:**

A few rare but serious occurrences of idiosyncratic reactions to acepromazine may occur in dogs following oral or parenteral administration. These potentially serious adverse reactions include behavioral disorders in dogs such as aggression, biting/chewing, and nervousness.

To report suspected adverse drug events, for technical assistance or to obtain a copy of the Safety Data Sheet (SDS), contact Covetrus® North America at (855) 724-3461.

For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or <http://www.fda.gov/reportanimalae>

### **Storage:**

Store at 20° - 25°C (68° - 77°F). Excursions permitted to 40°C (104°F).

### **How Supplied:**

Acepromazine Maleate Tablets are available in 10 and 25 mg quarter-scored tablets and are supplied in bottles containing 100 and 500 tablets.

NDC 11695-7034-1 – 10 mg – 100 tablets

NDC 11695-7034-2 – 10 mg – 500 tablets

NDC 11695-7033-1 – 25 mg – 100 tablets

NDC 11695-7033-2 – 25 mg – 500 tablets

Approved by FDA under ANADA # 200-757

### **Questions?**

(855) 724-3461

Distributed by:

Covetrus® North America

400 Metro Place North

Dublin, OH 43017

**covetrus.com**

Made in India

CC-AcepromazineTabPI-01

REV: 0624

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## Principal Display Panel - Bottle Label, 10 mg - 100 Tablets

**Covetrus**

NDC:11695-7034-1

**Acepromazine Maleate Tablets**

**10 mg**

**Caution:** Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Approved by FDA under ANADA # 200-757

**Net Contents:**

100 tablets

**Keep out of reach of children.**  
For use in dogs only.  
Keep Acepromazine Maleate Tablets in a secure location out of reach of dogs, cats, and other animals to prevent accidental ingestion or overdose.

Distributed by:  
Covetrus® North America  
Dublin, OH 43017  
Made in India  
CC-083641-L-01    REV: 0624

Lot: [Redacted]  
Exp: [Redacted]

**covetrus**

2098153  
NDC: 11695-7034-1

**Acephromazine Maleate Tablets**

**10 mg**

**Caution:** Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Approved by FDA under ANADA # 200-757

**Net Contents:**  
100 tablets    **Reorder #083641**

**Each tablet contains:**  
10 mg acepromazine maleate.

**Indications:** As an aid in tranquilization and as a preanesthetic agent in dogs.

**Dosage:** Dogs - 0.25-1.0 mg per lb of body weight. Dosage may be repeated as required.

Refer to package insert for complete product information.

**Storage:**  
Store at 20° - 25°C (68° - 77°F).  
Excursions permitted to 40°C (104°F).  
GUJ/DRUGS/G/25/2354

8  
40066  
51440  
9

95 mm (L)

41 mm (H)

No Varnished Area (Do Not Print)  
(20 x 12 mm)

## Principal Display Panel - Bottle Label, 10 mg - 500 Tablets

**Covetrus**

NDC:11695-7034-2

**Acepromazine Maleate Tablets**

**10 mg**

**Caution:** Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Approved by FDA under ANADA # 200-757

**Net Contents:**

500 tablets

**Keep out of reach of children.**  
For use in dogs only.  
Keep Acepromazine Maleate Tablets in a secure location out of reach of dogs, cats, and other animals to prevent accidental ingestion or overdose.

Distributed by:  
Covetrus® North America  
Dublin, OH 43017  
Made in India  
CC-083642-L-01 REV: 0624

Lot:  
Exp:

**covetrus**

NDC: 11695-7034-2

**Acepromazine Maleate Tablets**

**10 mg**

**Caution:** Federal law restricts this drug to use by or on the order of a licensed veterinarian.

**Each tablet contains:**  
10 mg acepromazine maleate.

**Indications:** As an aid in tranquilization and as a preanesthetic agent in dogs.

**Dosage:** Dogs - 0.25-1.0 mg per lb of body weight. Dosage may be repeated as required.

Refer to package insert for complete product information.

**Storage:**  
Store at 20° - 25°C (68° - 77°F).  
Excursions permitted to 40°C (104°F).

Approved by FDA under ANADA # 200-757

**Net Contents:**  
500 tablets

Reorder #083642

GUJ/DRUGS/G/25/2354

50.5 mm (H)

97 mm (L)

No Varnished Area (Do Not Print)  
(20 x 12 mm)

**Principal Display Panel - Bottle Label, 25 mg - 100 Tablets**

**Covetrus**

NDC:11695-7033-1

**Acepromazine Maleate Tablets**

**25 mg**

**Caution:** Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Approved by FDA under ANADA # 200-757

**Net Contents:**

100 tablets

**Keep out of reach of children.**  
For use in dogs only.  
Keep Acepromazine Maleate Tablets in a secure location out of reach of dogs, cats, and other animals to prevent accidental ingestion or overdose.

Distributed by:  
Covetrus® North America  
Dublin, OH 43017  
Made in India  
CC-083639-L-01    REV: 0624

Lot:   
Exp:   
No Varnished Area (Do Not Print)  
(20 x 12 mm)

**covetrus**

NDC: 11695-7033-1

**Acepromazine Maleate Tablets**

**25 mg**

**Caution:** Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Approved by FDA under ANADA # 200-757

**Net Contents:**  
100 tablets

**Reorder #083639**

**Each tablet contains:**  
25 mg acepromazine maleate.

**Indications:** As an aid in tranquilization and as a preanesthetic agent in dogs.

**Dosage:** Dogs - 0.25-1.0 mg per lb of body weight. Dosage may be repeated as required.

Refer to package insert for complete product information.

**Storage:**  
Store at 20° - 25°C (68° - 77°F).  
Excursions permitted to 40°C (104°F).

GUJ/DRUGS/G/25/2354

95 mm (L)

41 mm (H)

## PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

**Covetrus**

NDC:11695-7033-2

**Acepromazine Maleate Tablets**

**25 mg**

**Caution:** Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Approved by FDA under ANADA # 200-757

**Net Contents:**

500 tablets

**Keep out of reach of children.**  
For use in dogs only. Keep Acepromazine Maleate Tablets in a secure location out of reach of dogs, cats, and other animals to prevent accidental ingestion or overdose.

Distributed by:  
Covetrus® North America  
Dublin, OH 43017  
Made in India  
CC-083640-L-01 REV: 0624

Lot:    
Exp:

**covetrus**

NDC: 11695-7033-2

# Acepromazine Maleate Tablets

2098156

**25 mg**

**Caution:** Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Approved by FDA under ANADA # 200-757

**Net Contents:**  
500 tablets

Reorder #083640



**Each tablet contains:**  
25 mg acepromazine maleate.

**Indications:** As an aid in tranquilization and as a preanesthetic agent in dogs.

**Dosage:** Dogs - 0.25-1.0 mg per lb of body weight. Dosage may be repeated as required.

Refer to package insert for complete product information.

**Storage:**  
Store at 20° - 25°C (68° - 77°F). Excursions permitted to 40°C (104°F).

GUJ/DRUGS/G/25/2354

97 mm (L)

50.5 mm (H)

No Varnished Area (Do Not Print)  
(20 x 12 mm)

## ACEPROMAZINE MALEATE

acepromazine maleate tablet

### Product Information

<b>Product Type</b>	PRESCRIPTION ANIMAL DRUG	<b>Item Code (Source)</b>	NDC:11695-7034
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACEPROMAZINE MALEATE (UNII: 37862HP20M) (ACEPROMAZINE - UNII:54EJ303F0R)	ACEPROMAZINE MALEATE	10 mg

### Product Characteristics

<b>Color</b>	PINK (Light pink to peach)	<b>Score</b>	4 pieces
<b>Shape</b>	ROUND	<b>Size</b>	8mm
<b>Flavor</b>		<b>Imprint Code</b>	35;U
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11695-7034-1	100 in 1 BOTTLE		

2 NDC:11695-7034-2 500 in 1 BOTTLE

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200757	11/15/2024	

## ACEPROMAZINE MALEATE

acepromazine maleate tablet

### Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:11695-7033
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACEPROMAZINE MALEATE (UNII: 37862HP2OM) (ACEPROMAZINE - UNII:54EJ303FOR)	ACEPROMAZINE MALEATE	25 mg

### Product Characteristics

Color	YELLOW	Score	4 pieces
Shape	ROUND	Size	8mm
Flavor		Imprint Code	37;U
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11695-7033-1	100 in 1 BOTTLE		
2	NDC:11695-7033-2	500 in 1 BOTTLE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200757	11/15/2024	

**Labeler** - Covetrus North America (603750329)

**Registrant** - ZYVET ANIMAL HEALTH INC. (117047560)

